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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

In re ARDELYX, INC.	Case No. 4:21-cv-05868-HSG CLASS ACTION **SECOND AMENDED CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

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Lead Plaintiff Jatin Malhotra ("Plaintiff") makes the following allegations, individually and on behalf of all others similarly situated, by and through Plaintiff's counsel, upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, counsel's investigation, which included, among other things, review and analysis of: (i) regulatory filings made by Ardelyx Inc. ("Ardelyx" or "Company") with the United States Securities and Exchange Commission ("SEC"); (ii) press releases and media reports issued and disseminated by the Company; and (iii) analyst reports, media reports, and other publicly disclosed reports and information about the Company, including audio recordings from, and edited transcripts of, events during which the Company participated, and documents made publicly available by the United States Food and Drug Administration ("FDA").[1] Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein, after a reasonable opportunity for discovery.

SUMMARY OF THE ACTION

1. Plaintiff brings this federal securities action under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5) on behalf of a class consisting of all persons and entities, other than Defendants herein and their affiliates, who purchased or otherwise acquired Ardelyx securities between March 6, 2020 and July 19, 2021, inclusive ("Class Period"), and who were damaged as a result of Defendants' violations of the Exchange Act ("Class").

2. Ardelyx is a publicly traded biopharmaceutical company. During the relevant period, the focus of its business was developing and commercializing a drug called tenapanor to treat elevated serum phosphorus – a condition called hyperphosphatemia – in adult patients with chronic kidney disease ("CKD") on dialysis.

3. If approved for that indication, tenapanor would represent a first-in-class treatment for the control of serum phosphorus in adult patients with CKD on dialysis because of its novel

[1] The event transcripts reviewed were obtained through BamSEC, an online database accessible to subscribers, and were edited and prepared by Thomson Reuters unless otherwise indicated. The audio recordings were accessed from the Bloomberg Terminal.

mechanism of action. While existing drugs on the market for the treatment of hyperphosphatemia in adult CKD patients on dialysis act through the mechanism of binding to phosphates, tenapanor purportedly acts through the mechanism of inhibiting the cellular uptake of phosphates.

4. On or about June 30, 2020, Ardelyx submitted a New Drug Application ("NDA") to the FDA to obtain approval to sell and market tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. An NDA is the means by which a drug sponsor formally asks the FDA to approve a new drug for marketing and sale in the United States with respect to a given indication. Defendants told the public about that NDA on August 6, 2020. The FDA accepted, or agreed to review, Ardelyx's NDA on or about September 15, 2020, and set a Prescription Drug User Fee Act ("PDUFA") date of April 29, 2021. A PDUFA date is the date by which the FDA must respond to an NDA.

5. Because Defendants considered tenapanor their leading product candidate during the relevant period, the fate of Ardelyx's tenapanor NDA – *i.e.*, whether the FDA would approve or reject it – was integral to the valuation and future success of Ardelyx securities.

6. Throughout the Class Period, Defendants repeatedly assured the market that the FDA's approval was all but guaranteed because the FDA had already seen some of the data – as part of a prior FDA approval process for use of tenapanor as a treatment for irritable bowel syndrome – and, most critically, because the Company's meetings with the FDA were going well. For example, on November 17, 2020, speaking at an investor conference, Ardelyx's CEO, Defendant Mike Raab, stated with respect to the NDA, "So we're quite confident with what it is that we've submitted. ***The interactions [thus] far with the agency have gone exceedingly well*** . . . the confidence I have in the team and the confidence with the fact that they've seen the majority of this help a lot with the uncertainty . . . ." [Emphasis added.[2]] On February 24, 2021, at another conference, Raab stated:

> ***So, we're about to see the fruits of our labor presumably with an approval around our PDUFA date*** and then embark on the commercialization for the product.

* * *

[2] *See* Transcript of Jefferies Virtual London Healthcare Conference at 4 (Nov. 17, 2020) (accessed via the Bloomberg Terminal).

> ***All the interactions that we've had thus far with the agency are standard ones*** that you have throughout the process of requests that they have for data or clarifications. ***But there's been nothing untoward and anything that causes us concern***.

[Emphasis added.[3]]

7. These statements, and many others like them made during the Class Period, were false and misleading because Ardelyx was not having only "standard" meetings with the FDA that were going "exceedingly well" such that FDA approval could be all but "presum[ed]." Far from it. In fact, during a pivotal meeting, the FDA had raised substantial concerns that Ardelyx's clinical trial data – which it would submit in support of the NDA – had not shown a sufficiently quantifiable clinical benefit of administering tenapanor to treat hyperphosphatemia in adult CKD patients on dialysis. As the FDA has recently disclosed, in March 2020, Ardelyx officials met with the FDA. During that meeting, the FDA called into question Ardelyx's clinical trial data and stated that "while it ha[d] accepted serum phosphorus as a surrogate endpoint, a treatment effect of any magnitude is not considered sufficient to support approval." The FDA stated that Ardelyx needed to "address the clinical relevance of the magnitude of the treatment effect observed in their development program in [its] NDA submission" and that the FDA was "interested in the evidence supporting the conclusion that the magnitude of the treatment effect is clinically relevant, as opposed to 'expert opinion."' In the same regard, the FDA noted that there is "no evidence from outcome studies demonstrating that a treatment's effect on serum phosphorus predicts its effect on clinical outcomes." The Agency also stated that "showing a marked treatment effect in patients with more marked elevations in [serum phosphorus] level at baseline could be compelling."

8. The March 2020 meeting was a so-called Pre-NDA meeting. Such meetings typically occur after the conclusion of all clinical trials associated with a forthcoming NDA. Pre-NDA meetings focus primarily on administrative matters and occur no less than 60 days prior to the NDA filing. They seek to ensure that the forthcoming NDA submission is well-organized, properly formatted, with clinical data accurately presented, and set up for success. Ultimately

[3] While the Thomson Reuters transcript available on BamSEC.com indicates that Defendant Raab said "unpoured," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "untoward."

however, the objective of Pre-NDA meetings is to determine whether outstanding issues require additional data or studies.

9. Here, it was clear as of the March 2020 meeting, that Ardelyx's tenapanor NDA was in serious peril. The FDA had emphasized to Ardelyx that it needed to demonstrate the clinical relevance of the magnitude of the treatment effect by pointing to either a "marked treatment effect" on serum phosphorus levels in patients or by pointing to evidence from outcome studies. But Ardelyx did not have data showing the requisite "marked effect" and had not conducted an outcome study such that it was unclear how Ardelyx could satisfy the FDA's direction. For this reason, it was false and misleading for Defendants to assure investors that meetings with the FDA were going "exceedingly well" when, in fact, the FDA's comments concerning the data needed for approval pointed to huge hurdles that Ardelyx would need to overcome.

10. On July 19, 2021, the Company announced that the FDA had rejected the tenapanor NDA for the exact reasons outlined in the March 2020 meeting. That day, Ardelyx announced in a press release that it had received a letter from the FDA dated July 13, 2021, in which the agency stated it had found deficiencies in the tenapanor NDA that precluded discussion of the would-be labeling and post-marketing requirements for the drug. Critically, the FDA said it detected "deficiencies" in the clinical data Ardelyx had provided with respect to both "***the size of the treatment effect and its clinical relevance***." [Emphasis added.]

11. Immediately following the Company's July 19, 2021 disclosure regarding the deficiencies of the clinical trial data offered to support the tenapanor NDA, market analysts cut their price targets and downgraded the Company's rating. Piper Sandler, for example, rated Ardelyx neutral (down from a buy-equivalent rating) and wrote, "we struggle to see a path forward for Tenapanor." Raymond James, another analyst, reset the Company's price target to $4, from $14 per share.

12. The Company's share price likewise plunged, falling $5.69 per share – or nearly 74% – in a single day, to close at $2.01 per share on July 20, 2021, before falling another 4.22% by market close on July 21, 2021.

13. This lawsuit seeks to recover damages sustained as a result of Defendants' wrongdoing.

JURISDICTION AND VENUE

14. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

16. This Court has jurisdiction over each of the Defendants named herein because each is an individual or a corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

17. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). During the relevant period, Defendants conducted business in this District, and a substantial part of the events or omissions giving rise to the claims in this action – including Defendants' preparation and dissemination of materially false and misleading information as alleged herein – occurred in this District.

18. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Plaintiff

19. Lead Plaintiff Jatin Malhotra, as set forth in his previously filed certification, acquired and held shares of Ardelyx common stock at artificially inflated prices during the Class Period, and has been damaged as a result of the violations of the federal securities law alleged herein. (*See* ECF No. 45-2.)

B. Defendants

20. Defendant Ardelyx is a specialized biopharmaceutical company incorporated under the laws of the state of Delaware. At all relevant times prior to October 2021, Ardelyx was co-headquartered in Fremont, California (at 34175 Ardenwood Boulevard, Fremont, California 94555) and Waltham, Massachusetts (at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451). As of October 2021, and currently, the Company maintains its headquarters in Waltham, Massachusetts. Ardelyx's common stock is listed on the NASDAQ under the ticker symbol "ARDX."

21. Defendant Mike Raab was, throughout the Class Period and at all relevant times, President and Chief Executive Officer of the Company, positions he held since March 2009. Defendant Raab also serves as a director on Ardelyx's Board of Directors.

22. Defendant Justin Renz was, throughout the Class Period and at all relevant times, Chief Financial Officer of the Company, a position he held since June 2020.

23. Defendant David Rosenbaum was, throughout the Class Period and at all relevant times, Chief Development Officer of the Company, a position he held since January 2015. Together, Defendants Raab, Renz, and Rosenbaum are referred to herein as the "Individual Defendants."

24. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements, or to cause them to be corrected. Because of their position with the Company and access to material non-public information was available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and

were being concealed from, the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

I. ARDELYX AND TENAPANOR

25. Founded in 2007, Ardelyx is a biotechnology company focused on developing and commercializing therapies for, among other things, persons with kidney and cardiorenal disease. Ardelyx has been publicly traded since June 2014, and has not earned a profit in any fiscal year. Accordingly, at all relevant times, Ardelyx's financial well-being heavily depended on the commercial success of tenapanor for the treatment of hyperphosphatemia in adults with CKD who were on dialysis.

26. Ardelyx considers tenapanor its "lead product candidate." Ardelyx initially began developing tenapanor in or about 2009, to treat irritable bowel syndrome ("IBS") associated with constipation. For that indication only, Ardelyx obtained FDA approval in or about September 2019, to market and sell tenapanor in the United States, but the Company has neither commercialized nor generated any significant revenue from its sale for that indication yet. This failure to commercialize the IBS indication for tenapanor made the success of the CKD NDA, and subsequent commercialization of tenapanor as a treatment for CKD, even more important for Ardelyx.

27. As relevant here, Ardelyx has advanced another indication for tenapanor, namely, for the treatment of hyperphosphatemia in adult CKD patients on dialysis.

28. In the context of that indication, tenapanor represents a first-in-class therapy because of its novel mechanism of action. Extant medicines that treat hyperphosphatemia in adult CKD patients on dialysis act through the mechanism of binding to phosphates that enter the body. Tenapanor, by contrast, acts through the mechanism of inhibiting the paracellular uptake of phosphates. According to Ardelyx, tenapanor has "a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3," resulting in the "tightening of

the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption."

29. If approved, according to Ardelyx, tenapanor "would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake," and "could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal."

30. Thus, as presented by Defendants, obtaining FDA approval for tenapanor for treating hyperphosphatemia represented, and continues to represent, a lucrative commercial opportunity. The importance of that opportunity for Ardelyx was compounded by the Company's historical inability to report a profitable quarter as a publicly traded company.

II. ARDELYX'S NDA FOR TENAPANOR FOR HYPERPHOSPHATEMIA

31. Ardelyx presented tenapanor to the FDA based on a Phase 3 clinical trial program consisting of what it described as "three successful Phase 3 trials involving over 1,000 patients that evaluated the use of tenapanor." Phase 3 clinical studies also are known as "pivotal" studies because they generally contain the data that the FDA will use to determine whether to approve a proffered therapy for a given indication.

32. In general, a Phase 3 clinical trial uses a particular clinical trial endpoint to measure the results of the trial. An endpoint that directly measures the proposed clinical benefit of a therapy, such as reduced morbidity or mortality, is called a clinical outcome endpoint. An endpoint that measures something other than a clinical outcome is called a surrogate endpoint. A surrogate endpoint, in turn, must be shown to reliably predict the clinical benefit of a proposed therapy by virtue of the measured changes in the surrogate endpoint because, by design, a surrogate endpoint does not directly measure the clinical benefit.

33. Certain surrogate endpoints belong to the subclass called biomarkers. In general, a biomarker is a defined characteristic that is measured objectively as an indicator of the body's response to an exposure or intervention, including a therapeutic intervention.

34. Given the inherent limitations on the utility of surrogate endpoints (and the clinical trial data that relies on them), the FDA publishes and maintains a table of surrogate endpoints "that have either been already used in development programs for drugs that have been approved, or surrogate endpoints that [the] FDA has indicated acceptance of in guidance[] or other documents." The purpose of that table is to "provide valuable information for drug developers on endpoints that may be considered and discussed with [the] FDA for individual development programs," and to "facilitate consideration of potential surrogate endpoints when developers are designing their drug development programs." The FDA also is required by statute to publish that information.

35. The FDA instructs that the acceptability of using even those surrogate endpoints included on its table depends "in part on the disease, studied patient population, therapeutic mechanism of action, and availability of current treatments." As the FDA instructs further: "A particular surrogate endpoint that may be appropriate for use in a particular drug or biologic clinical development program, should not be assumed to be appropriate for use in a different program that is in a different clinical setting."

36. Each of the three Phase 3 trials that Ardelyx used to support the tenapanor NDA (collectively referred to herein as the "Phase 3 Trials") used a surrogate endpoint instead of a clinical outcome endpoint. The relevant surrogate endpoints all related to levels of serum phosphates measured in trial participants (which may be further characterized as a biomarker). That means the Phase 3 Trials measured the changes in serum phosphorus among participants that could be attributed to the use of tenapanor. By design, the Phase 3 Trials did not measure whether, or to what extent, any clinical benefits flowed from those changes in serum phosphorus, such as reduced morbidity or mortality.

37. As relevant here, however, "serum phosphates" appear on the FDA's table of surrogate endpoints for the indication of hyperphosphatemia only where the "[d]rug mechanism of action" is phosphate binding. Put differently, there is no precedent for the successful use of serum phosphates as a clinical endpoint where, as here, the drug's mechanism of action is inhibiting phosphate uptake – rather than binding to phosphates – to treat hyperphosphatemia.

38. In March 2020, several senior Ardelyx officials attended a Pre-NDA meeting with FDA personnel. On information and belief, this meeting occurred at FDA headquarters in Maryland and the Ardelyx officials that attended included Chief Scientific Officer Jeff Jacobs, Chief Regulatory Officer Rob Blanks, and Chief Development Officer David Rosenbaum. Also present on behalf of Ardelyx was Dr. Glenn Chertow, Division Chief of Nephrology and Professor of Medicine at Stanford University. FDA attendees included senior members of the Office of Cardiology, Hematology, Endocrinology, and Nephrology ("OCHEN") including OCHEN Director Dr. Ellis Unger and Deputy Director Dr. Aliza "Lisa" Thompson.

39. Pre-NDA meetings typically occur after the conclusion of all clinical trials associated with a forthcoming NDA. Pre-NDA meetings focus primarily on administrative matters and occur no less than 60 days prior to the NDA filing. They seek to ensure that the forthcoming NDA submission is well-organized, properly formatted, with clinical data accurately presented, and set up for success. Ultimately however, the objective of Pre-NDA meetings is to determine whether outstanding issues require additional data or studies.

40. The March 2020 meeting did not focus significantly on administrative matters. Rather, the meeting focused on questions about tenapanor's efficacy in treating hyperphosphatemia in adult CKD patients on dialysis. Specifically, the FDA raised the concern that the magnitude of the treatment effect as shown in the Phase 3 Trials may not be clinically relevant. Indeed, during this meeting, the FDA clearly informed Ardelyx that while it had accepted serum phosphate as a surrogate endpoint, a "treatment effect of any magnitude is not considered sufficient to support [NDA] approval."

41. During the Pre-NDA meeting, these clinical issues were discussed at length. The minutes of the meeting state:

> "The Agency indicated that it has accepted serum phosphorus as a surrogate endpoint and basis for approval for products intended to treat hyperphosphatemia in patients with chronic kidney disease in dialysis. The evidence supporting its use as a surrogate endpoint includes biologic plausibility and epidemiologic data; ***but, to date there is no evidence from outcome studies demonstrating that a treatment's effect on serum phosphorus predicts its effects on clinical outcomes***." ***The Agency clarified, however, that while it has accepted serum phosphorus as a surrogate endpoint, a treatment effect of any magnitude is not considered sufficient to support approval***.

> The Agency indicated that the Applicant should address the clinical relevance of the magnitude of the treatment effect observed in their development program in their NDA submissions. ***The Agency stated that it is interested in evidence supporting the conclusion that the magnitude of the treatment effect is clinically relevant, as opposed to "expert opinion."*** The Agency also stated that showing a marked treatment effect in patients with more marked elevations in s-P level at baseline could be compelling.[4]

[Emphasis added.]

42. Thus, based on the FDA's demand for evidence supporting the conclusion that the magnitude of the treatment effect was clinically relevant, Defendants knew that Ardelyx's NDA was in serious jeopardy. Ardelyx did not have data showing a "marked" decline in serum phosphorus levels caused by administering tenapanor, and it did not have data from outcome trials demonstrating clinical relevance. In other words, Ardelyx did not have the "evidence" that the FDA said it wanted to see to support approval.

43. Although Defendant Raab later posited that the FDA's denial of the tenapanor NDA resulted from the FDA having "moved the goalposts," the concerns raised by the FDA during the Pre-NDA meeting were not unique. To the contrary, prior to the Pre-NDA meeting, the FDA made comments to Ardelyx that were consistent with the concerns it raised in the Pre-NDA meeting. These previous comments emphasized the FDA's ongoing concern with the magnitude of tenapanor's treatment effect, and the clinical relevance associated therewith.

44. In November 2017, for example, the FDA provided Ardelyx with feedback in connection with the Phase 3 Study TEN-02-301, where the FDA stated, in pertinent part, "If the size of the effect of tenapanor on serum phosphorous is significantly smaller than the size of the effect of currently approved phosphate binders, then you will need to address the clinical relevance of the effect size of your product on serum phosphorous."[5]

45. In December 2018, the FDA issued a so-called "Advice Letter" in response to Ardelyx's request for feedback in connection with the above-referenced Phase 3 study. Ardelyx's

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[4] *See FDA Briefing Document, NDA # 213931*, at 12 (Nov. 16, 2022), https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-16-2022-meeting-cardiovascular-and-renal-drugs-advisory-committee-meeting-announcement#event-materials [hereinafter *FDA Briefing Document*].

[5] *See FDA Briefing Document* at 11.

request pertained to labeling questions, specifically, whether the results of the Phase 3 study could support additional labeling claims. In response, the FDA very pointedly qualified its remarks by stating, in pertinent part, "***Assuming*** the trial is well-conducted and ***the size of the treatment effect is clinically relevant***, we agree that the results could be described in labeling."[6]

46. During the Pre-NDA meeting, the FDA stressed that it sought "evidence supporting the conclusion that the magnitude of the treatment effect is clinically relevant, as opposed to 'expert opinion.'" During the Class Period, Ardelyx worked with and pointed to various nephrologists who had collectively said that phosphate reduction was clinically beneficial to dialysis patients. With the above remark made during the Pre-NDA meeting, the FDA very clearly indicated that this "expert opinion" by itself, which Ardelyx had trumpeted in support of its NDA, would likely be insufficient.

47. On information and belief, Defendant Raab was aware that during the Pre-NDA meeting, the FDA had emphasized the need for Ardelyx to more compellingly and quantifiably demonstrate evidence of clinical benefit. Defendant Raab had conversations with other senior Ardelyx officials regarding the FDA's comments and how Ardelyx should respond. Nevertheless, Defendant Raab and Ardelyx's other senior leadership decided to ignore the FDA's comments and just move forward with the NDA.

48. On August 6, 2020, in a press release titled "Ardelyx Reports Second Quarter 2020 Financial Results and Recent Business Highlights," Ardelyx announced that on June 30, 2020, it submitted an NDA to the FDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. An NDA is the means by which a drug sponsor formally asks the FDA to approve a new drug for marketing and sale in the United States with respect to a given indication. The Company reported substantially the same news in its quarterly report on Form 10-Q for the period ending June 30, 2020, which it filed with the SEC the same day.

49. On September 15, 2020, Ardelyx announced that the FDA had accepted, or agreed to review, its NDA for tenapanor, for the treatment of hyperphosphatemia in adult CKD patients

[6] *FDA Briefing Document* at 11.

on dialysis. The Company did so in a press release titled "Ardelyx Announces FDA Acceptance for Filing of Its New Drug Application of Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis." Also in that press release, Ardelyx relayed that the FDA had set a PDUFA date – *i.e.*, the date by which the FDA would respond to the NDA – of April 29, 2021.

50. On April 29, 2021, roughly ten months after Ardelyx submitted the tenapanor NDA, the Company announced that the FDA pushed back the PDUFA date it initially set by three months. In the relevant press release the Company issued titled, "Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis", Ardelyx stated that the FDA "made a recent information request that required the company to submit additional analyses to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies." According to Ardelyx, that information request came after the parties already had begun "constructive labeling discussions" regarding tenapanor which, if true, would have been a positive development. "Labeling discussions" refers to the process for determining what disclosures, warnings and other information must be included with a drug when it is sold to patients. Typically, the FDA does not discuss labeling requirements for drugs that are unlikely to receive FDA approval.

51. The next key update Ardelyx provided on the tenapanor NDA occurred several months later, on July 19, 2021, when the Company announced that the FDA had sent it a letter six days earlier (on July 13, 2021) in which the agency "identified deficiencies that preclude[d] discussion of labeling and post-marketing requirements" for tenapanor. The "deficiencies" the FDA identified included, according to Ardelyx, "the size of the treatment effect and its clinical relevance" pursuant to the Phase 3 Trials. The Company made that update in a press release titled "Ardelyx Provides Regulatory Update on New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis."

52. As detailed herein, at all relevant times, Defendants knew (or recklessly disregarded) that the Phase 3 Trials' use of serum phosphates as surrogate endpoints – which never

had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used, and which the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context – materially weakened the ability of the clinical data in the tenapanor NDA to demonstrate a clinically relevant treatment effect of the drug that would deliver, or be likely to deliver, FDA approval of a first-in-class medicine. Because demonstrating such clinical relevance was integral to the tenapanor NDA; in turn, Defendants misled investors about the likelihood that the FDA would approve the NDA.

III. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

53. Throughout the Class Period, Defendants misleadingly portrayed the FDA as having acquiesced to Ardelyx's NDA approach, such that approval was all but assured. Contrary to Defendants' representations, the reality was that the FDA had raised serious concerns that Ardelyx's data based on the Phase 3 Trials did not demonstrate a clinical benefit of administering tenapanor to treat hyperphosphatemia in adults CKD patients on dialysis, such that approval of the NDA was in serious doubt.

A. March 6, 2020 8-K

54. The March 6, 2020 SEC Form 8-K stated:

> **On-Track to Submit NDA for Tenapanor for the Control of Serum Phosphorus in mid-2020:** Ardelyx is on-track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for tenapanor for the control of serum phosphorus in mid-2020.

[Emphasis added.]

55. The foregoing was false and misleading in light of the failure to disclose the FDA's concerns that Ardelyx had not sufficiently demonstrated that tenapanor had a clinical benefit in treating hyperphosphatemia in adult CKD patients on dialysis. Only recently, prior to March 6, 2020, Defendant Raab stated to the market that he expected smooth sailing with respect to Ardelyx's NDA based on his prior interactions with the FDA. For example, at a February 26, 2020 healthcare conference, Defendant Raab stated:

> We will submit our NDA mid-this year. I think an important note there is, with the approval of the IBS-C NDA, remember the same drug substance, same exact ratio

> of excipient to active. So the FDA has already seen all the CMC, cardiorenal actually consulted with GI as the data package and the safety package had for renal clinical trials in it. So whatever risk there is to CMC, I think that's been, for the most part, mitigated. The only thing we need to add to the package is the AMPLIFY and the PHREEDOM studies. So we expect that approval. We're being conservative 12 months, 10 plus 2, maybe '21 for approval. We're beginning the process of building the pre-commercial efforts and the team that we're going to need for that.[7]

56. Thus, in context, Ardelyx's 8-K misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor, and would, therefore likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research.

B. May 7, 2020 Press Release

57. In a May 7, 2020 press release, the Company stated the following:

> **Preparing NDA Submission for Tenapanor for the Control of Serum Phosphorus in mid-2020**: With strong data from its clinical program for tenapanor, Ardelyx is preparing a New Drug Application for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis, which the company currently intends to submit to the U.S. Food and Drug Administration in mid-2020.

[Emphasis added.]

58. The foregoing was false and misleading, because, in context, it misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor, and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

[7] *See* Transcript of 9th Annual SVB Leerink Global Healthcare Conference at 2 (Feb. 26, 2020) (accessed via the Bloomberg Terminal).

C. August 6, 2020 Quarterly Report

59. On August 6, 2020, Ardelyx filed with the SEC its quarterly report on Form 10-Q for the period ending June 30, 2020 ("2Q20 10-Q"). In relevant part, with respect to the tenapanor NDA and underlying Phase 3 Trials, the 2Q20 10-Q stated:

> Our portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis, for which we completed the Phase 3 clinical program and have submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") on June 30, 2020. Based on standard FDA review timelines, we expect to receive notification from the FDA on the acceptance of the filing for substantive review by early September 2020. Tenapanor for the control of serum phosphorus has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 ("NHE3"). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. Three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels, as either monotherapy or as part of a dual mechanism approach with phosphate binders, have been reported.
>
> We have evaluated tenapanor in a Phase 3 program for the control of serum phosphorus in CKD patients on dialysis. In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, which achieved statistical significance for the primary endpoint***. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE Phase 4 study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
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> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been***

> ***shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, as such we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

60. The foregoing misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor, and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

D. August 6, 2020 Press Release

61. The same day, in the Company's press release accompanying its 2Q20 10-Q, Ardelyx announced that it had submitted the tenapanor NDA to the FDA "for the review of tenapanor as a first-in-class therapy to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis." Quoting Defendant Raab, the press release stated:

> "Over the last quarter, we continued to make critical progress towards our goal of providing our first-in-class therapy tenapanor to adult CKD patients on dialysis with elevated serum phosphorus, a condition, despite traditional therapies, that has been associated with poor survival outcomes," said Mike Raab, president and chief executive officer of Ardelyx. "This past June, we submitted a New Drug Application to the FDA for this indication, and we expect to receive notification of its acceptance for substantive review and our PDUFA date by early September. ***As part of our filing, we included additional, robust data reconfirming tenapanor's ability to lower and control serum phosphorous levels at a rate better than those reported with phosphate binders alone***. In addition, during the quarter, we augmented our senior leadership team with the hiring of an experienced chief commercial officer and chief financial officer as we prepare for launch and evolving into a revenue-generating company."

[Emphasis added.]

62. Under the heading "Recent Business and Pipeline Updates," the August 6, 2020 press release also stated that the NDA "filing is supported by ***three successful Phase 3 studies*** demonstrating tenapanor's ability to reduce phosphate levels, with two trials evaluating tenapanor

as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders." The press release also reported "additional positive data from the ongoing NORMALIZE Phase 4 study," which was an extension of one of the three Phase 3 Trials that remained ongoing. [Emphasis added.]

63. The foregoing statements were materially false, misleading, incomplete, and inaccurate (both individually and in combination) because, in context, they misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

E. September 14, 2020 H.C. Wainwright 22nd Annual Global Investment Virtual Conference and September 17, 2020 Cantor Fitzgerald Virtual Global Healthcare Conference

64. On September 14, 2020 H.C. Wainwright investor conference, Ardelyx's CFO, J. Renz, stated:

> We have three successful ***statistically significant*** Phase 3 studies that David will take us through. ***We submitted our NDA in June and we expect approval*** in the middle of next year. Tenapanor should have a large target market with approximately $2.7 million prescriptions written each year in the United States. And we've built a very impressive U.S. specialty focused commercial organization. We're building that out over the next several quarters as ***we prepare for approval next year***.[8]

[Emphasis added.]

65. Similarly, at a September 17, 2020 Cantor Fitzgerald Conference, CEO Raab stated:

> We have great partnerships in Canada, China and Japan with Knight, Fosun and KKC and ***continued to build upon those as we get this NDA approved***, ***we would***

[8] *See* Transcript of H.C. Wainwright 22nd Annual Global Investment Virtual Conference at 1 (Sept. 14, 2020) (accessed via the Bloomberg Terminal).

> ***then be able to provide them the NDA that they would then use*** in Canada and China to filing their respective regulatory bodies.[9]

[Emphasis added.]

66. The foregoing statements were false and misleading because they, individually and when read together, served to assure investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

F. November 5, 2020 Quarterly Report

67. On November 5, 2020, Ardelyx filed with the SEC, on Form 10-Q, its third quarter 2020 financial results ("3Q20 10-Q"), repeating substantially the same claims made in the Company's 2Q20 10-Q with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the 3Q20 10-Q stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
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> * * *
>
> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, which achieved statistical significance for the primary endpoint***. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.

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[9] *See* Transcript of Cantor Fitzgerald Virtual Global Healthcare Conference at 6 (Sept. 17, 2020) (accessed via the Bloomberg Terminal).

> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
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> * * *
>
> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

68. The foregoing misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

G. November 5, 2020 Press Release

69. In the November 5, 2020 press release accompanying the 3Q20 10-Q – titled "Ardelyx Reports Third Quarter 2020 Financial Results and Business Highlights" – Ardelyx again used the relevant clinical trial data as a centerpiece. Quoting Defendant Raab, the press release stated:

> "The FDA's acceptance of our New Drug Application for tenapanor is a major milestone that continues our progress toward the potential launch of this novel therapeutic for the many dialysis patients who struggle with controlling hyperphosphatemia," said Mike Raab, president and chief executive officer of

> Ardelyx. "Our commitment to this field was further highlighted in ***clinical data presented at ASN Kidney Week 2020 generated by Ardelyx and our Japanese partner KKC, supporting the clinical safety and efficacy of tenapanor and reinforcing its potential to transform the treatment landscape for patients***."

[Emphasis added.]

70. Under the heading "Recent Business and Pipeline Updates," the November 5, 2020 press release also stated:

> The United States Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for tenapanor to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis with a Prescription Drug User Fee Act ("PDUFA") goal date of April 29, 2021. ***The filing was supported by three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels***, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders.
>
> ***Presented new clinical data supporting the clinical safety and efficacy of tenapanor*** at ASN Kidney Week 2020. Three poster presentations highlighted data from Phase 3 trials conducted by Ardelyx, including the BLOCK, AMPLIFY and PHREEDOM studies. Additionally, the company's partner for tenapanor in Japan, Kyowa Kirin Co., Ltd., presented the results from two Phase 2 studies evaluating the efficacy and safety of tenapanor in Japanese patients on hemodialysis.

[Emphasis added.]

71. The statements set out above were materially false, misleading, incomplete, and inaccurate (both individually and in combination) because they assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

H. November 17, 2020 Investor Presentation

72. Defendants Raab and Rosenbaum, gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format, at the Jefferies Virtual London Healthcare Conference on November 17, 2020. Ardelyx published notice that the Company would be making that

presentation – which it called a "fireside chat" – in a November 10, 2020 press release titled "Ardelyx to Present at the Jefferies Virtual London Healthcare Conference."

73. During the presentation, a participant asked about the clinical development program Ardelyx was conducting for the tenapanor NDA. In response, Defendant Rosenbaum stated that the data from the Phase 3 Trials established that administering tenapanor produced "a significant and clinically relevant phosphate lowering":

> Q – But David for the clinical program, I guess what is the goal? What is it that we're trying to do for these patients? And how in your view did your clinical program demonstrate [ ] the achievement of those goals?
>
> A – [Rosenbaum] Sure. So first it's well known a lot of prospective observational studies that have shown an association with elevate[d] [serum phosphorus] and morbidity mortality. A lot of studies have shown that, so what our goal here is to lower serum phosphorus. And we've shown – we've run as Mike said three Phase 3 clinical trials two short term one long term. ***And what we've shown is that if you dose tenapanor [alone], you get a significant and clinically relevant phosphate lowering***. In our long-term phase 3, which is the most relevant study, we showed that 77% [of] people administered tenapanor had a decrease in serum phosphorus and there was a 2 mg/dL decrease. So that's a very significant effect.
>
> * * *
>
> And those on tenapanor, we automatically add tenapanor and allow them to titrate off of [sevelamer] to see how many we can get into the normal range. And people who end up studying from the beginning of freedom had a means prosperous of 7.27 mgs per deciliter. After mean duration of around 19 to 20 months, they went down to 4.94. And so they had over 2.3 mg definitely decrease and we were able to get up to 47% of those people into the normal range. So around the 60% increase over standard of c[a]re. ***So, what that – totality of that data [has] shown is that you can treat a lot of people with tenapanor alone and it will work well***.[10]

[Emphasis added.]

74. During the same presentation, a participant asked about the status of Ardelyx's tenapanor NDA, in response to which Defendant Raab stated that relevant divisions of the FDA "ha[d] already seen" certain information in the tenapanor NDA by virtue of the Company's prior submission of an NDA for tenapanor for the treatment of irritable bowel syndrome associated with constipation ("IBS-C"):

> Q – Okay. All right. Well very good. And so [ ] the NDA submission is completed [at] this point, right?

[10] *See* Transcript of Jefferies Virtual London Healthcare Conference at 3 (Nov. 17, 2020) (accessed via the Bloomberg Terminal).

* * *

> A – [Defendant Raab] Yes . . . And we've been guiding the traditional 10 plus 2 PDUFA. Now the fact that we have, the idea CNDA is actually 10 month PDUFA, neither first the full 12. ***So, as we communicate and have people understand the FDA has already seen the entire CMC*** [Chemistry, Manufacturing, and Controls] ***package, but for the dosage forms***, 10 20 and 30, ***they've seen majority [of] the clinical data and in fact cardiorenal consulted with GI*** [the gastrointestinal division] ***on the [renal] studies that were in that data package. So we're quite confident with what it is that we've submitted. The interactions [so] far with the agency have gone exceedingly well,*** will there be an inspection who knows with COVID (Technical Difficulty) person, the confidence I have in the team and the confidence with the fact that they've seen the majority of this helps a lot with the uncertainty we all feel until COVID has passed.[11]

[Emphasis added.]

75. The foregoing statements were materially false, misleading, incomplete, and inaccurate (both individually and in combination) because they misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting. It was further false and misleading to claim that meetings with the FDA were going "exceedingly well" in light of the fact that the FDA had raised serious concerns about the evidentiary support for the NDA.

I. February 24, 2021 Investor Presentation

76. Defendant Raab gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format at the 10th Annual SVB Leerink Global Healthcare Conference on February 24, 2021. Ardelyx published notice that the Company would be making that presentation – which

[11] *See* Transcript of Jefferies Virtual London Healthcare Conference at 4 (Nov. 17, 2020) (accessed via the Bloomberg Terminal). While the transcript indicates that Defendant Raab said "cardiorenal consulted with GI on the *green all* studies," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "cardiorenal consulted with GI on the *renal* studies."

it called a "fireside chat" – in a February 17, 2021 press release titled "Ardelyx to Present at the 10th Annual SVB Leerink Global Healthcare Conference."

77. During the presentation, Defendant Raab was asked about the status of Ardelyx's tenapanor NDA, in response to which he emphasized that certain divisions of the FDA "ha[d] seen a good portion of this package" when Ardelyx previously had submitted an NDA for tenapanor for the treatment of IBS-C. Defendant Raab espoused points substantially similar to those he made during the November 17, 2020 investor call in which he partook months before, purporting to leverage Ardelyx's prior successful tenapanor NDA for IBS-C as a favorable indicator of things to come:

> Q – Maybe this is a good time to ask you about how the FDA review is coming along and your confidence level in a timely approval, especially considering that at least in the last couple of months, some companies saw a delay due to COVID. Do you worry about that at all?
>
> A – Yes. I mean we always worry because you don't know until you know. And I think we've got confidence in this, though, because remember that this is – tenapanor has already been approved for another indication. So this NDA is what the FDA has already seen.
>
> And in fact, cardiorenal division consulted the GI [gastrointestinal] division for the approval of IBSRELA for IBS-C. Now IBSRELA is sitting on the shelf, but the benefit of that process we went through, both with the inspections that we went through as well as cardiorenal having seen a good portion of this package gives us confidence that the PDUFA date of April 29 is not something that's at massive risk.
>
> ***All the interactions that we've had thus far with the agency are standard ones that you have throughout the process of requests that they have for data or clarifications. But there's been nothing [untoward] and anything that causes us concern.***[12]

[Emphasis added.]

78. The foregoing misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns at the March 2020 meeting, for example, that Ardelyx's data did not

[12] While the Thomson Reuters transcript available on BamSEC.com indicates that Defendant Raab said "unpoured," an audio recording of the same presentation accessed from the Bloomberg Terminal confirms Defendant Raab said "untoward."

demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. It was also false and misleading to claim that the Company was only having "standard" meetings with the FDA and that there was no cause for "concern," when the FDA had raised serious concerns about the evidentiary basis for the NDA that Ardelyx had failed to address.

J. March 8, 2021 Annual Report

79. On March 8, 2021, Ardelyx filed with the SEC on Form 10-K its fourth quarter and full year 2020 financial results ("FY20 10-K"), repeating substantially the same claims made in the Company's 2Q20 10-Q and 3Q20 10-Q, with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the FY20 10-K stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
>
> * * *
>
> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint***. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate***

> ***produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
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> * * *
>
> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***.

[Emphasis added.]

80. The foregoing misleadingly assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

K. April 29, 2021 Press Release

81. On April 29, 2021 – the date the FDA initially set as the operative PDUFA date for the tenapanor NDA – Ardelyx issued a press release titled, "Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis," announcing that the FDA made a request for additional information "***to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies***." [Emphasis added.] The Company reported that it "submitted the requested analyses" to the FDA in response to the request, which "constitute[d] a major amendment" to the NDA that required extending the PDUFA date "by three months" to July 29, 2021. [Emphasis added.]

82. Quoting Defendant Raab, the press release stated,

> "While disappointed in the delay, we understand the impact that the COVID-19 pandemic has had on the operations of the agency," said Mike Raab, president and chief executive officer of Ardelyx. "We appreciate the constructive labeling discussions with the agency over the past month and ***believe that the additional***

> ***analyses submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence we generated on tenapanor***. We look forward to continuing to work closely and constructively with FDA during the remainder of the review process. We are confident in the comprehensive data set, are well prepared for the launch of tenapanor upon potential approval and are dedicated to bringing this important medicine to patients."
>
> The NDA for tenapanor for the control of serum phosphorus is supported by a comprehensive development program involving more than 1,000 patients, including ***three Phase 3 clinical trials, all of which met their primary and key secondary endpoints***.

[Emphasis added.]

83. The statements set out above were materially false, misleading, incomplete, and inaccurate (both individually and in combination) because they continued to assure investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

L. May 6, 2021 Quarterly Report

84. On May 6, 2021, Ardelyx filed with the SEC on Form 10-Q, its first quarter 2021 financial results ("1Q21 10-Q"). With respect to the tenapanor NDA and underlying Phase 3 Trials, the Company repeated substantially the same claims made in its preceding quarterly SEC filings that spoke to the topic even though less than two weeks earlier the FDA formally requested more information "to better understand the clinical data" from those trials. The 1Q21 10-Q expressed nothing of substance about the FDA's information request, and stated, in relevant part:

> On April 29, 2021, the U.S. Food and Drug Administration ("FDA") determined that a submission we made in response to an information request from the FDA constituted a major amendment to our New Drug Application ("NDA") for tenapanor for the control of serum phosphorus, resulting in a three-month extension of the PDUFA date to July 29, 2021. ***The FDA's information request included a request for additional analyses of our clinical data***.
>
> * * *

> In December 2019***, we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint***. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
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> * * *
>
> Tenapanor is the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***.

[Emphasis added.]

85. The foregoing was false and misleading because it continued to assure investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants

as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

M. May 6, 2021 Press Release

86. As reported in the May 6, 2021 press release accompanying the Company's release of its First Quarter 2021 Financial Results, Defendant Raab offered an optimistic take on the FDA's request for clarifying information, stating in relevant part:

> "We continue to prepare for the potential approval and launch of tenapanor following the recent extension of our PDUFA date to July," said Mike Raab, president and chief executive officer of Ardelyx. "***We remain confident in the comprehensive data included in our New Drug Application*** and believe tenapanor represents an attractive alternative to currently available therapies to control serum phosphorus in CKD patients on dialysis. To that end, we are committed to working with the FDA through the completion of its review of our NDA and look forward to the possibility of making a significant impact in the lives of patients."

[Emphasis added.]

87. The statements set out above were materially false, misleading, incomplete, and inaccurate because they assured investors that the NDA had an extremely high chance of success and that the FDA was supportive of the NDA, when the reality was that the FDA had raised serious concerns that Ardelyx's data did not demonstrate a clinical benefit of treating CKD patients with tenapanor and would, therefore, likely be insufficient to support FDA approval of the NDA in the NDA's current form and without additional scientific studies and research. The FDA's concerns were well known to Defendants, as evidenced by, among other things, the FDA's statements to the Company at the March 2020 meeting.

IV. THE TRUTH EMERGES

88. Defendants' unduly rosy narrative came to a screeching halt after the markets closed on July 19, 2021. That day, Ardelyx announced the FDA sent the Company a letter six days earlier (on July 13, 2021), in which the FDA stated it identified "deficiencies" with respect to "***the size of the treatment effect and its clinical relevance***" based on the clinical trial data Ardelyx provided in the tenapanor NDA. [Emphasis added.] Notably, this issue was the one raised by the FDA in the March 2020 pre-NDA meeting and that Defendants' concealed with their blithe assurances that the FDA meetings were going exceedingly well.

89. The press release Ardelyx published on the topic stated, in relevant part:

> [T]oday [Ardelyx] announced that it received a letter from the U.S. Food and Drug Administration (the "FDA") on July 13, 2021, stating that, as part of its ongoing review of the company's New Drug Application ("NDA") for the control of serum phosphorus in adult patients with chronic kidney disease ("CKD") on dialysis, ***the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time***. The letter stated that the notification does not reflect a final decision on the information under review. The company immediately requested a meeting to discuss the deficiencies and was notified by the FDA today that the request for a meeting was denied.
>
> While the FDA has not provided specific details regarding the deficiencies, ***the FDA noted that a key issue is the size of the treatment effect and its clinical relevance***.
>
> "This is an extremely disheartening and disappointing communication from the FDA, particularly following the weeks of label discussions that occurred in early April, the fact that our NDA submission included three pivotal trials across 1,000 patients, all which met their primary and key secondary endpoints, as well as the additional data analyses we submitted in late April in response to the FDA's requests," said Mike Raab, president and chief executive officer of Ardelyx. "We plan to work with the FDA to learn more about the identified deficiencies and will seek to resolve them as quickly as possible."

[Emphasis added.]

90. These disclosures informed the market that, contrary to Defendants' claims, Ardelyx was not having "standard" meetings with the FDA that were going "exceedingly well." On this news, the price of Ardelyx's shares plunged from their July 19, 2021 closing price of $7.70 per share, to a July 20, 2021 close of just $2.01 per share. This represents a one-day drop of nearly 74%, or hundreds of millions of dollars in lost market capitalization.

91. Then, on July 29, 2021 – the operative PDUFA date following the major amendment to the NDA Ardelyx reported on April 29, 2021 – the Company issued a press release announcing that it "***received a Complete Response Letter***" from the FDA in response to the tenapanor NDA. [Emphasis added.] A Complete Response Letter ("CRL") is a response to an NDA by which the FDA tells a drug sponsor its review of the NDA is complete and the agency is not approving the application. The relevant press release was titled "Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis."

92. According to Ardelyx, in relevant part, the Complete Response Letter stated the FDA determined "***the magnitude of the treatment effect***" shown in the tenapanor NDA and underlying clinical trial data was "***small and of unclear clinical significance***":

> [T]oday [Ardelyx] announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.
>
> According to the CRL, while the FDA agrees that "the submitted data provide substantial evidence that tenapanor is effective in reducing serum phosphorus in CKD patients on dialysis," ***they characterize the magnitude of the treatment effect as "small and of unclear clinical significance***." Additionally, the FDA noted that for the application to be approved, Ardelyx needs "to conduct an additional adequate and well-controlled trial ***demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis***." There were no safety, clinical pharmacology/biopharmaceutics, CMC [chemistry, manufacturing, and controls] or non-clinical issues identified in the CRL.
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> * * *
>
> "We are saddened by this communication from the FDA and what it means for the patients and the physicians who treat them," said Mike Raab, president and chief executive officer of Ardelyx. "We continue to believe tenapanor represents an important, first-in-class treatment option for patients with elevated phosphorus. We do not agree with the FDA's subjective assessment on ***the clinical relevance of the treatment effect of tenapanor in our studies which met all clinical endpoints agreed upon by the FDA***. In our view, the serum phosphorus lowering data generated with tenapanor in all of our clinical studies is meaningful and clinically significant. We will work with the agency to address the issues raised and, to the extent possible, find an expeditious path forward."

[Emphasis added.]

93. The CRL letter further stated that "there is no precedent for accepting treatment effects of the magnitude seen in this development program."

94. The Company convened a conference call with investors later that day to discuss the issuance of the CRL. On the call, Defendant Raab repeatedly represented that ***the FDA had authorized, and even helped design, the clinical trials*** it now found incapable of demonstrating a clinically relevant treatment effect of tenapanor for hyperphosphatemia in adult CKD patients on dialysis:

> How we got here sales comprehension, especially considering the extensive and comprehensive clinical evaluation of tenapanor with three successful Phase 3 trials, all of us which met primary and key secondary endpoints with statistical significance compared to placebo and long-term safety demonstrated versus

> inactive safety control, ***all three Phase 3 trials were designed and agreed upon in collaboration with the FDA***, not to mention that tenapanor was approved in September 2019 to treat irritable bowel syndrome and constipation in adults.
>
> * * *
>
> The clinical data supporting our NDA involve over 1000 patients and included two Phase 3 monotherapy trials and a Phase 3 trial of tenapanor in combination with binder therapy. Our development program encompassed years of clinical investigation and valuation. ***As you would expect, all of our trial designs were discussed and shared with the FDA every step of the way***. Results from a rigorous statistical analysis plan demonstrated clear, unambiguous, and consistent safety and efficacy of tenapanor in reducing serum phosphorus. Furthermore, we continue to develop and share more supportive data from our ongoing Phase 4 studies normalized and optimized at international medical and scientific meetings.
>
> * * *
>
> ***During each step of development, we reviewed our trial designs with statistical analysis plans with the FDA***, including powering the freedom study to achieve at least a 1 milligram per deciliter decrease in serum phosphorus which tenapanor readily achieved. These interactions coupled with the scenes[ph] approval of tenapanor or IBSC, let us to feel quite confident heading into the NDA process for the use of tenapanor in hyperphosphatemia.

[Emphasis added; alteration in original.]

95. During the question-and-answer segment of that conference call, a participant asked the pointed question: "Are we hearing that maybe [the FDA's] cardiorenal [division] was maybe reconsidering whether or not phosphorous is an approval biomarker?" Defendant Raab answered:

> I think what we're hearing is Cardiorenal ***inherited phosphorus as a biomarker that has been used to approve other products***. I think what I'm hearing is ***they're not seeing or believing in the clinical relevance of the effect***, although they say it in their letter. And we've hit every single endpoint. I think they're asking us to prove something potentially that doesn't – haven't had to prove, but not knowable until we had the type A meeting.

[Emphasis added.]

96. Months later, during an investor presentation at the Jefferies London Healthcare Virtual Conference on November 18, 2021, Defendant Raab said the FDA's decision reflected the agency having "***moved… the goalposts*** on us [by] implying that they would expect an outcome type study":

> [A –] We clearly have a statistically significant impact on decreasing serum phosphorus whether it's a monotherapy or when you're adding it with binders, and

> you're having an impact. And physicians should be able to make those decisions based upon what the clinical data are that you have generated [from your] clinical studies. ***They have moved the [ ]goalposts on us, implying that they would expect an outcome type study*** which has never been required for phosphorus lowering drugs and that's a big part of our approach [is] to see – this is an acceptable endpoint. We hit the endpoint as we discussed and agreement is physical analysis plan. So we should address this in labeling and make sure that we have something that allows physicians to make a determination as to which patients are going to benefit from this.
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> * * *
>
> [Q –] Okay, all right. And so, like what would be – to the extent that you can, could you speculate on the things that somebody like a Peter Stein [Director of the Office of New Drugs of the FDA's Center for Drug Evaluation and Research] would take into account during their assessment?
>
> [A –] I think everything we just talked about, right. ***This is a program that follow[ed] the rules, right. And provided results that [ ] by any measure should have resulted in an approval, but for the fact that this division is not keen on surrogate endpoints, the biomarkers***. This is the Cardio-Renal Division inherited hyperphosphatemia from the metabolic endocrine division and have only approved two other drugs, Velphoro and Auryxia, but those are binders, right. And that was the rationale, that's within a family or a class of drugs and similar endpoint nor new mechanism of action and different biology. I think gave them the opportunity and you could say it that way to then [hold us] to a different standard, which is my speculation on, so what [a Peter Stein] would do is look at what we generated and the argument that we will [pose] is that having followed all the rules and [hit] the endpoints as anticipated, this is a drug that is approvable.

[Emphasis added.]

97. Thus, according to Defendants, the FDA's decision on the tenapanor NDA was caused by the FDA "mov[ing] the goalposts" on the agency's view of using serum phosphorus levels as a surrogate endpoint in the Phase 3 Trials. But the problem for Defendants is that they were told by the FDA that it had serious concerns long before receiving the CRL.

98. Following the issuance of the CRL, the Company undertook steps to appeal the denial of the tenapanor NDA through the FDA's formal dispute resolution procedures. First, the Company appealed to the Office of Cardiology, Hematology, Endocrinology and Nephrology, which the FDA denied. Then the Company appealed to the Office of New Drugs, which convened an Advisory Committee meeting of the Cardiovascular and Renal Division. On November 16, 2022, the Advisory Committee decided, by a nine-to-four vote of its members, that the benefits of administering tenapanor to adult CKD patients on dialysis outweighed its risks for the control of

serum phosphorus as a monotherapy. The Committee also decided, by a ten-to-two vote of its members (with one member abstaining), that the benefits of tenapanor outweighed its risks when administered in combination with phosphate binders.

99. Although the vote of the Advisory Committee was not binding on the Office of New Drugs in ruling on the Company's second-level appeal of the issuance of the CRL, the Office of New Drugs granted the appeal on December 29, 2022. The grant of that appeal does not amount to an approval of the tenapanor NDA. Rather, the FDA directed the Company that it must submit a new NDA for tenapanor to treat hyperphosphatemia in adult CKD patients on dialysis. On December 29, 2022, the Company announced it intended to do so in the first half of 2023.

V. ADDITIONAL SCIENTER ALLEGATIONS

100. As alleged herein, Defendants acted with scienter in that they: (i) knew that the public documents and statements issued or disseminated in the name of the Company were materially false, misleading, and incomplete when made; (ii) knew that such statements or documents would be issued or disseminated to the investing public; and (iii) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. The Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding the Phase 3 Trials data, their control over, and/or receipt and/or modification of Ardelyx's allegedly materially false, misleading, and incomplete statements and/or their associations with the Company that made them privy to confidential proprietary information concerning Ardelyx, participated in the fraudulent scheme alleged herein.

101. Specifically, at all relevant times, Defendants knew (or recklessly disregarded) that the purportedly successful Phase 3 Trials were incapable of demonstrating a clinically relevant treatment effect sufficient to deliver, or be likely to deliver, FDA approval of the tenapanor NDA. Despite that, Defendants serially brandished the Phase 3 Trials as showing that tenapanor delivered a successful and clinically relevant treatment of hyperphosphatemia in adult CKD patients on dialysis, even after the FDA requested clarifying information that supposedly disrupted the parties'

label discussions. Indeed, the FDA expressed its concerns about the Company's data and forthcoming NDA ***before the NDA was submitted*** in a meeting with the Company in March 2020, where the FDA expressly asked how the Company intended to demonstrate a clinical benefit.

102. Moreover, scienter can be inferred from the importance of obtaining FDA approval for tenapanor to treat hyperphosphatemia in adult CKD patients on dialysis to the "core operations" of Ardelyx. For example, as the Company stated in both its 2Q20 10-Q and 3Q20 10-Q, Ardelyx's "portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis." Further, although Ardelyx previously obtained FDA approval of its NDA of tenapanor for the treatment of IBS-C, Ardelyx "ha[s] not generated any revenues from product sales" yet, as both the 2Q20 10-Q and 3Q20 10-Q indicated. Recognizing the commercial importance of tenapanor to Ardelyx, Defendant Raab emphasized that the Company had become "well positioned and well prepared to commercialize tenapanor upon potential FDA approval of the first and only phosphate absorption inhibitor for the control of serum phosphorus" in a March 8, 2021 press release titled "Ardelyx Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Highlights." At bottom, at all relevant times, obtaining FDA approval for tenapanor for hyperphosphatemia was critical to Ardelyx's commercial prospects.

103. During the Class Period, Defendant Raab sold 230,067 shares of Ardelyx. In 2019, Raab sold 29,698 shares of Ardelyx. In January and February 2020, when Ardelyx's share price was elevated by the expectation of the commercialization of tenapanor, Raab sold 25,000 shares of Ardelyx. Between July 20, 2021 and December 31, 2022, Raab sold 128,342 shares of Ardelyx and bought 3,000 shares.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

104. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 103 above as if fully set forth herein.

105. Plaintiff brings this action as a class action, pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class consisting of all those who purchased,

or otherwise acquired Ardelyx's common stock, during the Class Period, and were damaged upon the revelation of the alleged corrective disclosure (the "Class").

106. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of Ardelyx, members of the Company's Board of Directors, and members of their immediate families (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing persons' legal representatives, heirs, successors, or assigns; and (iv) any entities in which Defendants have or had a controlling interest, or any affiliate of Ardelyx.

107. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's common stock was actively traded on the NASDAQ, a national securities exchange in the United States. While the exact number of Class members is unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the Class. Millions of Ardelyx shares were publicly traded during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Ardelyx or its transfer agent, and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

108. Plaintiff's claims are typical of the claims of Class members because all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws as alleged herein.

109. Plaintiff will fairly and adequately protect the interests of Class members, and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

110. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the members of the Class are:

(a) whether Defendants violated the Exchange Act as alleged herein;

(b) whether Defendants' statements to the investing public during the Class Period omitted and/or misrepresented material facts about the Company;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants Raab and Renz caused Ardelyx to issue false and misleading statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(f) whether the price of Ardelyx's common stock was artificially inflated; and

(g) whether the members of the Class have sustained damages, and, if so, what is the proper measure of damages.

111. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable.

112. Further, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this Action as a class action.

PRESUMPTION OF RELIANCE

113. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Ardelyx's common stock is traded in an efficient market;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company's securities were traded on the NASDAQ in the United States;

(f) the Company was covered by securities analysts;

(g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(h) Plaintiff and members of the Class purchased, acquired, and/or sold Ardelyx's common stock between the time the Defendants failed to disclose, or misrepresented material facts, and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

114. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

115. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

CLAIMS FOR RELIEF

COUNT I

Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

116. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 115 above, as if fully set forth herein.

117. This Count is asserted on behalf of all members of the Class against Ardelyx and the Individual Defendants for violations of §10(b) of the Exchange Act (15 U.S.C. §78(b)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

118. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under

which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Ardelyx's common stock; and (iii) cause Plaintiff and other members of the Class to purchase, or otherwise acquire, Ardelyx's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

119. Pursuant to the above plan, scheme, conspiracy, and course of conduct, Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases, and other statements and documents, as described above, including statements made to securities analysts and the media, that were designed to influence the market for Ardelyx's common stock. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Ardelyx's business and operations.

120. By virtue of their positions at Ardelyx, the Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein, and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Individual Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew, or recklessly disregarded, that material facts were being misrepresented or omitted, as described above.

121. Further information showing that Defendants acted knowingly, or with reckless disregard for the truth, is peculiarly within Defendants' knowledge and control. As senior managers and/or directors of Ardelyx, the Individual Defendants had knowledge of the details of Ardelyx's internal affairs.

122. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants Raab and Renz were able to, and did, directly or indirectly, control the content of the statements of Ardelyx. As officers and/or directors of a publicly held company, Defendants Raab and Renz had a duty to disseminate timely, accurate, truthful, and complete information with respect to Ardelyx's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Ardelyx's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Ardelyx's business and financial condition, which were concealed by Defendants, Plaintiff and other members of the Class purchased, or otherwise acquired Ardelyx's common stock, at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or statements disseminated by Defendants, and were damaged thereby.

123. During the Class Period, Ardelyx's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Ardelyx's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased, or otherwise acquired, said common stock, or would not have purchased or otherwise acquired shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Ardelyx's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Ardelyx's common stock declined sharply upon public disclosure of the facts alleged herein, to the injury of Plaintiff and Class members.

124. By reason of the conduct alleged herein, Defendants have knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

125. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

126. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

COUNT II

Violations of §20(a) of the Exchange Act
(Against the Individual Defendants)

127. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 126 above, as if fully set forth herein.

128. During the Class Period, the Individual Defendants participated in the operation and management of Ardelyx and conducted and participated, directly and indirectly, in the conduct of Ardelyx's business affairs. Because of his senior positions as the Company's CEO and President, Defendant Raab knew of the materially false and misleading information alleged herein. Similarly, because of his senior position as the Company's CFO, Defendant Renz knew of the materially false and misleading information alleged herein.

129. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, with respect to Ardelyx's business practices, and promptly correct any public statements issued by Ardelyx that had become materially false or misleading.

130. Because of their positions of control and authority as senior directors, and/or officers, and/or executive team members of the Company, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Ardelyx disseminated in the marketplace during the Class Period concerning the Company's business, operations, and the tenapanor NDA. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Ardelyx to engage in the wrongful acts complained

of herein. The Individual Defendants, therefore, were each a "controlling person" of Ardelyx within the meaning of §20(a) of the Exchange Act. In this capacity, the Individual Defendants participated in the unlawful conduct alleged herein, that artificially inflated the market price of Ardelyx's common stock.

131. The Individual Defendants, therefore, each acted as a controlling person of Ardelyx. By reason of their senior management positions and/or being a director of Ardelyx, the Individual Defendants had the power to direct the actions of, and exercised the same, to cause Ardelyx to engage in the unlawful acts and conduct complained of herein. The Individual Defendants exercised control over the general operations of Ardelyx, and possessed the power to control the specific activities that comprise the primary violations, about which Plaintiff and the other members of the Class complain.

132. As set forth above, Ardelyx and the Individual Defendants each violated §10(b) and Rule 10b-5 promulgated thereunder by their acts and omissions, as alleged in this complaint.

133. By reason of the above conduct and by virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class have suffered damages in connection with their purchases of the Company's securities.

134. This action is filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23, and certifying Plaintiff as the Class Representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre- and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff hereby demands a trial by jury on all issues so triable.

DATED: April 14, 2023

SCOTT+SCOTT ATTORNEYS AT LAW LLP

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